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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/003,718 | 10/26/2001 | David Ternes | 279.405US1 | 2631 |
| 21186 | 7590 | 09/13/2005 | | |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938 | | | EXAMINER OROPEZA, FRANCES P | |
| | | | ART UNIT 3762 | PAPER NUMBER |

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/003,718 | TERNES ET AL. | |
| | Examiner | Art Unit | |
| | Frances P. Oropeza | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7/19/05 (Amendment).
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-33,35 and 37 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15-21,25-31 and 35 is/are rejected.
- 7) Claim(s) 22-24,32,33 and 37 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/3/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 15, 17-21, 25-31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (US 5458623) in view of Sun et al. (US 5755739) and Kroll (EP 1155711 A2).

Lu et al. disclose a capture threshold determination system comprising a pacemaker (22), external programmer (10) and cable with surface electrode (18) (abstract; col. 1 @ 9-14; col. 3 @ 1-20 and 26-29; col. 23 @ 46 – col. 4 @ 29; col. 4 @ 45 – col. 5 @ 6; col. 5 @ 14-18). Lu et al. disclose the claimed invention except for two pacing channels (claims 15 and 26) and the comparison using time-domain correlation.

As to two pacing channels, Sun et al. teach waveform discrimination using two pacing channels for the purpose of effectively directing stimulation signals to the cardiac tissue. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used two pacing channels in the Lu et al. system in order to provide stimulation flexibility enabling enhanced detection of auto-capture (abstract; fig. 1; col. 1 @ 27-57; col. 8 @ 10-52).

As to time-domain correlation, Sun et al. teaches signal analysis using time-domain correlation for the purpose of enhancing the classification of rhythms. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used time-domain correlations in the Sun et al. system in order to effectively evaluate the signal morphology so the point of loss of capture is clearly defined (col. 5 @ 6-19).

As discussed in the previous three paragraphs of this action, modified Lu et al. discloses the claimed invention except for each of the pacing pulses being delivered collectively by the pacing channels.

Kroll et al. teaches biventricular stimulation using simultaneous cross-chamber pacing (pacing pulses being delivered collectively by the pacing channels) for the purpose of overcoming the issue of lead polarization. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used pacing pulses being delivered collectively by the pacing channels in the modified Lu et al. system in order to more accurately detecting capture, hence avoiding the false positive detections of an evoked potential which in leads to missed heartbeats, a highly undesirable and potentially life-threatening situation (paragraphs 0001, 0014, 0015, 0019, 0021).

2. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (US 5458623) in view of Sun et al. (US 5755739) and Kroll (EP 1155711 A2) and further in view of Callaghan et al. (US 4895152). As discussed in paragraph 1 of this action, modified Lu et al. disclose the claimed invention except for an evoked response sensing channel.

Callaghan et al. teach cardiac pacing using an evoked response sensing channel (54) for the purpose of enabling evaluation of the cardiac stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an evoked response sensing channel in the modified Lu et al. system in order to have a proven means that clearly determines the effectiveness of the cardiac stimulation (figure 5; col. 5 @ 3-20).

Allowable Subject Matter

3. Claims 22-24, 32, 33 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

MO
a-10-05


Robert E. Pezzuto
Supervisory Patent Examiner
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